



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/287,884	04/07/99	WANEBO	H 58463/JPW/EM

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EXAMINER

GOLDBERG, J

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

09/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/287,884

Applicant(s)

Wanebo

Examiner

Jerome D. Goldberg

Group Art Unit

1614



☒ Responsive to communication(s) filed on Aug 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicants elected the synergistic combination of C₆-ceramide and taxol with traversed in Paper No. 6. Claims are being examined as they read on the elected combination. Applicants' remarks are noted but one synergistic combination of drugs is patentably distinct from another synergistic combination of drugs and will support a separate patent.

Claims 1, 2 and 4-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific tumor and/or cancer disclosed, does not reasonably provide enablement for the term "tumor" and/or "tumor cells" and "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms "tumor cells" in claims 1, 4-11, 16 and 18, "tumor" in claims 2, 4-10 and 17 and "cancer" in claims 11-15 and 19 lack clear exemplary support in the specification as filed.

The cancer therapy art remains highly unpredictable, and no examples exist for efficacy of a combination of drugs against cancers or tumors generally. Therefore, based on the unpredictable nature of the invention and state of the prior art, lack of guidance and working example, and extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claims 1-13 and 15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific antitumor chemotherapeutic agent ^{and} ~~an~~ ceramide disclosed, does not reasonably provide enablement for the terms "antitumor chemotherapeutic agent" and "a ceramide". The specification does not enable any person skilled in the art to which

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it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms "antitumor chemotherapeutic agent" in claims 1-6, 8-13, and 15 and "a ceramide" in claims 1-5 and 7-13 lack clear exemplary support in the specification as filed.

Claims 14 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 19 are improperly drawn to the same method. Correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the WO 94/04541 reference taken with the Jayadev et al. reference of record. The WO 94/04541

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reference teaches the synergistic combination of taxol and sphingosine, the core compound of the ceramide claimed, (see claim 25 and ABSTRACT) for treating cancer. The Jayadev et al. reference teaches the C₆-ceramide as an anticancer agent. The references do not teach the combination of C₆-ceramide and taxol. Accordingly, one skilled in this art would be motivated to substitute the C₆-ceramide for the sphingosine in the primary reference synergistic combination since the core structure are the same and both compound are anticancer agents.

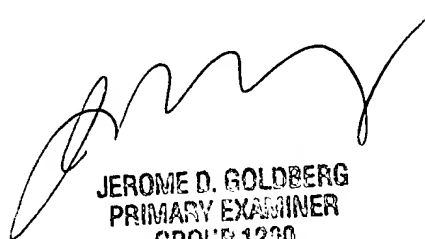
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg, whose telephone number is (703) -308-4606. The examiner can normally be reached on Monday through Thursday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) -308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) -308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Goldberg/LR

September 21, 2000



JEROME D. GOLDBERG
PRIMARY EXAMINER
GROUP 1230